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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,638	12/14/2000	Olivier De La Charriere	016800-429	6191

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/735,638

Applicant(s)

DE LA CHARRIERE ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26, 28-50, 53, 54, 116 and 121 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26, 28-50, 53-54, 116 and 121 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment dated 4-20-05 is acknowledged.

Claims included in the prosecution are 26, 28-50, 53-54, 116 and 121.

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 26, 28, 32-34, 45-46, 116 and 121 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/14084.

Instant claims are drawn to a method of treatment of a sensitive skin wherein substance P has already been released due to the exposure to and contact with one substance P release active agent.

WO teaches a method of treatment of skin by the topical application of the claimed P antagonists for the treatment of diseases such as pruritus and urticaria. The compositions are in the form of ointments, creams, lotions and various other forms and contain other additives and therapeutic agents. (note the abstract, page 5, lines 19-20,

pages 12-14 and claims). Since WO teaches the application of a substance P antagonist and since the function of an antagonist is to nullify the action of the agent against which it has the antagonist action, the reference reads on instant claims.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant once again argues that WO does not teach the treatment of conditions because of already released substance P. Applicant further argues that WO is directed to antagonizing binding or interaction of substance P with NK2 receptors and that NK@ receptors are not found in the smooth muscles and not in the skin. These arguments are not found to be persuasive. WO teaches the treatment of conditions such as pruritus and urticaria. This means that the substance P is already released since without such release the disease conditions would have manifested. Therefore, such a release is implicit in the teachings of WO.

Claim Rejections - 35 U.S.C. § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 26, 28, 32-34, 45-46, 116 and 121 are rejected under 35 U.S.C. § 103 as being unpatentable over WO 93/14084.

As pointed out above, this publication teaches a method of treatment of skin by the topical application of the claimed P antagonists for the treatment of diseases such as pruritus and urticaria. The compositions can be in the form of ointments, creams,

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lotions and various other forms and contain other additives and therapeutic agents.

(note the abstract, page 5, lines 19-20, pages 13-14 and claims). WO does not provide any specific examples for the topical application to the sensitive skin wherein the substance P is already released. However, based on the teachings of WO it would have been obvious to one of ordinary skill in the art to use the substance P antagonists taught by WO to counter the irritant side effects of a substance in the cosmetic composition due to the release of substance P since the antagonists counter the substance P.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again pertain to the already released substance P. The examiner has already addressed this issue above. Applicant further argues that the rejection over WO 084 does not give full consideration to all of the claim elements and that patentable weight must be given to "having such amount of substance P already released therein, " and "by exposure to and contact with at least one substance P antagonist effective to reduce or eliminate such amount of said already released substance P". These arguments are not persuasive. With regard to the first point, that is, "having such amount of substance P already released therein, as already pointed out above, the disease conditions would not have manifested in a subject if the substance P has not been released. With regard to the second issue, that is, "by exposure to and contact with at least one substance P antagonist effective to reduce or eliminate such amount of said already released substance P", the examiner points out that WO teaches the application of substance P antagonist to the skin of the

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subjects who show these conditions and it would have been obvious to one of ordinary skill in the art that the amount of a therapeutic agent would depend upon the conditions of the manifested conditions. Since the severity of the condition depends upon the released substance P, it would have been obvious to one of ordinary skill in the art that the therapeutic amounts taught by WO would be proportional to the substance P released.

5. Claims 26, 28-50, 53-54, 116 and 121 are rejected under 35 U.S.C. § 103 as being unpatentable over Wallengren (contact Dermatitis), Wallengren (BR. J. Dermatitis) in combination with WO 83/01252, WO 93/14084 individually or in combination (all are of record).

Wallengren (Contact dermatitis) teaches that the substance P antagonist Spantide diminishes the contact dermatitis caused by nickel sulfate (note the abstract and page 351).

Similarly, Wallengren (Br. J) teaches the inhibiting effect of substance P antagonists against various irritants (note abstract the entire article).

The teachings of WO 93 have been discussed above.

The WO 83 discloses the use of a peptide substance P antagonist in medicinal preparations including topical formulations (abstract, page 8 and claims).

In essence, these references teach implicitly that substance P has already been released in the host skin. It would thus, be obvious to one of ordinary skill in the art that application of an antagonist to already released substance P to nullify its effect.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again pertain to the already released substance P. The examiner has already addressed this issue above. Applicant also argues that the added claim 121 distinguishes from the cited prior art because it excludes "itching" and "pruritus" as symptoms of the sensitive skin being treated. This exclusion will not overcome the rejection because one of the symptoms recited is 'discomfort' and WO 83 teaches the action of the substance P antagonist on skin inflammation (page 3, lines 15-16). It would be obvious to one of ordinary skill in the art that 'discomfort' is associated with inflammation.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK